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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,134	03/11/2004	Gregory H. Altman	032794-054911-CIP	6963

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1657

MAIL DATE	DELIVERY MODE
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05/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/800,134

Applicant(s)

ALTMAN ET AL.

Examiner

David M. Naff

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 4-49 is/are pending in the application.
- 4a) Of the above claim(s) 32-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 4-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

An amendment of 2/8/07 amended claim 1, and canceled claim 3.

Claims in the application are 1, 2 and 4-49.

Claims 32-49 are withdrawn from further consideration pursuant to
5 37 CFR 1.142(b) as being drawn to a nonelected invention, there being
no allowable generic or linking claim. Election was made **without**
traverse in the reply filed on 9/6/06.

Claims examined on the merits are 1, 2 and 4-31.

The text of those sections of Title 35, U.S. Code not included in
10 this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C.
112:

15 The specification shall contain a written description of the invention, and of the
manner and process of making and using it, in such full, clear, concise, and exact
terms as to enable any person skilled in the art to which it pertains, or with
which it is most nearly connected, to make and use the same and shall set forth the
best mode contemplated by the inventor of carrying out his invention.

20 Claims 1, 2 and 4-31 are rejected under 35 U.S.C. 112, first
paragraph, as failing to comply with the written description
requirement. The claim(s) contains subject matter which was not
described in the specification in such a way as to reasonably convey
to one skilled in the relevant art that the inventor(s), at the time
25 the application was filed, had possession of the claimed invention.

Support is not found in the specification for "that retain their
native protein structure and have not been dissolved and

reconstituted" in claim 1. The page and line should be pointed out where this recitation occurs in the specification.

Claim Rejections - 35 USC § 103

5 Claims 1, 2 and 4-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al (6,303,136 B1) in view of O'Brien (7,014,807 B2) and Lewis et al (5,994,099) and Takezawa et al (5,736,399).

10 The claims are drawn to a fabric comprising a yarn comprising one or more sericin-extracted fibroin fibers that retain their native protein structure and have not been dissolved and reconstituted, and that are biocompatible and non-randomly organized. The yarn promotes ingrowth of cells and is biodegradable.

15 Li et al disclose attaching cells to a filamentous matrix that can be made from various materials including silk (col 2, line 49 and col 4, line 18).

 O'Brien discloses making yarn from fibroin fibers from which sericin has been extracted (col 2, line 64 and col 3, lines 45-48).

20 Lewis et al disclose preparing a matrix from silk for use in reconstruction of bone and connective tissue (col 21, lines 1-5).

 Takezawa et al disclose using a silk mesh as a culture carrier (col 5, lines 56-60).

25 It would have been obvious to use as the filamentous matrix of Li et al a yarn produced from fibroin fibers from which sericin has been removed as disclosed by O'Brien in view of Lewis et al suggesting

preparing a matrix for tissue reconstruction from silk and Takezawa et al using a silk mesh as a culture carrier. The conditions of dependent claims would have been matters of obvious choice in view of the disclosures of the references. Not dissolving as disclosed by
5 O'Brien would have been obvious when dissolving is not desired.

Response to Arguments

Applicants have pointed out the subject matter disclosed by each reference, and how the invention differs therefrom. However, the rejection is based on the references in combination, and the invention
10 becomes obvious when the references are considered together as a whole rather than each alone. It would have been obvious to use as the filamentous matrix of Li et al a yarn produced from fibroin fibers from which sericin has been removed as disclosed by O'Brien in view of Lewis et al suggesting preparing a matrix for tissue reconstruction
15 from silk and Takezawa et al using a silk mesh as a culture carrier. Such fibers will be degradable. It would have been obvious not to dissolve as disclosed by O'Brien and Lewis et al if the function of dissolving is not desired. The rejection is not based on using the suture of Takezawa et al.

Double Patenting

Claims 1, 2 and 4-31 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,902,932 B2 in view of O'Brien.

The claims of the patent require a silk-fiber-based matrix
25 composition comprising sericin-extracted silkworm fibroin fibers.

O'Brien is described as above.

It would have been obvious to provide the matrix of the claims of the patent as a fabric as suggested by O'Brien disclosing forming fabric from sericin-extracted silkworm fibroin fibers. The conditions of dependent claim would have been matters of obvious choice in view of the patent claims and O'Brien. As set forth above, it would have been obvious to omit the dissolving of O'Brien if the function of dissolving is not desired. Moreover, the claims of the patent do not require dissolving.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

5 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be
10 obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see [http://pair-](http://pair-direct.uspto.gov)
15 [direct.uspto.gov](http://pair-direct.uspto.gov). Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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David M. Naff
Primary Examiner
Art Unit 1657